REMARKS

Claims 8-14 and 46-65 are pending in the application. With this response, claims 12-14, 51-53, 57, 58, 60, 63, and 65 have been amended to correct for typographical errors.

After entry of the current amendment, claims 8-14 and 46-75 will be pending and in front of the examiner for consideration.

Claim Rejections - 35 U.S.C. § 103

The Office Action has rejected all of the pending claims under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al. (U.S. Patent No. 5,320,624; herein referred to as "Kaplan") in view of Stinson (U.S. Patent No. 6,245,103; herein referred to as "Stinson").

Claims 54-58 and 61-65

Claims 54-58 and 61-65 are rejected as being unpatentable over Kaplan in view of Stinson. Rejection of these claims is traversed as failing to support a conclusion of *prima facie* obviousness.

For a claim to be rejected as *prima facie* obvious, cited prior art must be shown to teach or suggest all features of a claim. The rejection, based on the cited Kaplan and Stinson references, does not support a showing of all of the features of Applicants' claims 54-58 and 61-65, including a "walled structure having fenestrations."

The Office Action, at page 3, states that relative to claim 54, "see fenestrations (openings) between the strand crossings of Stinson." The Examiner appears to be using the term "fenestration" to refer to any opening in a stent structure, and in doing so viewing claim 54 to encompass stent embodiments having structure formed from monofilaments and that includes openings between the monofilaments.

However, Applicants' specification and claims make clear that stent embodiments wherein the stent has a "fenestrated" wall are different from stent embodiments wherein the stent has monofilaments braided to form a stent wall. In particular, "fenestrated" stents, as described and illustrated, include wall structures that include apertures or holes that are molded or cut into a wall, and do not include holes or apertures formed from

braided monofilament fibers. The former and latter, according to Applicants' specification and claims, are separate embodiments of different stent structures of the invention. Applicants directs Examiner to page 8, lines 20-24, of the specification for clarification regarding these two embodiments, e.g., "fenestrations 24 are molded, laser cut, die cut, or machined in the wall of the tube." See also the text from page 9, line 27 through page 10, line 2. Moreover, Applicants' use of the terms "fenestration" and "fenestrated," in the present claims and specification, in referring to particular stent embodiments having apertures, holes, or windows that are molded, cut, or machined into a wall (as opposed to being apertures between braided monofilaments) is consistent with how these terms are commonly used by those of skill in the stent arts. Thus, these terms should be given their accepted meaning, which is consistent with the present specification, in reviewing the claims for patentability.

"When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art." *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

Taking into consideration the correct meaning of the term "fenestrations," as recited in claim 54, it is readily apparent that Stinson does not describe any stent having fenestrations as recited in claims 54-58 and 61-65. Additionally, the Kaplan reference contains no description of stents of any kind. The cited references, therefore, do not teach or suggest all the features as recited in the Applicants' claims. The requirements necessary for supporting a *prima facie* case of obviousness of claims 54-58 and 61-65 have not been met, and the outstanding rejection should be withdrawn.

Claims 8-14, 46-53, and 59-60

Claims 8-14, 46-53, and 59-60 were also rejected as being unpatentable over Kaplan in view of Stinson. Section 2143 of the MPEP states requirements of *prima facie* obviousness:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or

references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

The rejection of claims 8-14, 46-53, and 59-60 is traversed as failing to support a conclusion of *prima facie* obviousness. Specifically, the Office action does not include an adequate showing of the requisite suggestion or motivation, found within the cited references themselves, that would have provided a motivation to combine the separate aspects of their teachings, to produce a device of the invention as claimed, including a bioresorbable stent prepared from a blend of homopolymers. The cited references, in combination, fail to suggest a bioresorbable stent comprising a blend of homopolymers.

According to the Office Action, Kaplan is said to describe specific blends of biodegradable polymers - but does not describe stents. Kaplan lists suitable surgical devices that can be manufactured from the polymer blends, e.g., at column 6, lines 10-12. These include, "fasteners, such as staples, clips and the like and other implant devices, such as pins, bone screws, or the like." Kaplan goes on to describe how the polymer blends can improve impact resistance and crazing of a bone screw, and would allow the bone screw to be torqued to a greater extent without the likelihood that the screw would craze and become ineffective for its intended purpose (column 6, lines 21-39).

The Examiner acknowledges that Kaplan fails to disclose "a stent." Then, the Examiner implies that it perhaps would have been "inherent" in Kaplan to fabricate a stent from the blend of copolymers as disclosed by Kaplan -- or -- alternatively, concludes that it would have been obvious to do so to one with ordinary skill in the art "based on manufacturing and surgical considerations from the teachings of Stinson."

With respect to the implication of inherency, such a basis of rejection would be a misapplication of the law. Generally, issues of inherency concern a *property* that may be inherent in a particular object or composition of matter, in the context of anticipation (not obviousness). The rejection fails to provide any explanation of the asserted "inherency" of a stent in the Kaplan reference. Should the Examiner wish to maintain the rejection of Applicants' claims on these grounds, Applicants request that the Examiner further clarify the legal and factual basis of the rejection.

The Examiner, in the alternative, asserts that it would have been obvious to manufacture a stent using the polymeric materials of Kaplan, based on the teachings of Stinson. The totality of the reasoning offered to support the general rejection of claims, is as follows:

> to fabricate a stent from the blend of homopolymers as disclosed by Kaplan would have been obvious to one with ordinary skill in the art based on manufacturing and surgical considerations from the teachings of Stinson. (Emphasis ours.)

In view of the specific shortcomings of the cited references, the offered basis of rejection fails to support a conclusion of *prima facia* obviousness.

Again, the primary cited reference, Kaplan, is said to describe polymeric materials for preparing "surgical devices." The reference fails to describe or suggest that these materials be used to produce a bioresorbable stent, as claimed. The Kaplan reference describes "surgical devices" to include items "such as staples, clips and the like and other implant devices, such as pins, and bone screws, or the like." These types of devices do not specifically suggest stents, and are not asserted to suggest stents according to the rejection. Instead, the rejection relies on the Stinson reference to support the use of the Kaplan polymeric materials with a stent.

But, the Office action fails to offer a valid showing of a suggestion or motivation to combine the Kaplan reference with the Stinson reference, to result in a stent as claimed.

The sole rationale offered by the Office action to combine the cited references is the vague concept of "manufacturing and surgical considerations." This rationale utterly fails to support the rejection, e.g., as being one or more of: factually incorrect based on the content of the cited references, or otherwise not sufficiently specific to support a conclusion of a *prima facie* rejection.

"Manufacturing and surgical considerations" of Stinson would necessarily relate to bioresorbable stents. One of skill, based on the Stinson reference, would have prepared a bioresorbable stent as described in the Stinson reference, and without specific motivation would not have used the Kaplan materials as a replacement for the materials of the Stinson reference. Kaplan does nothing to disrupt the teachings of Stinson with regard to stent materials. Kaplan describes surgical devices that are not stents, and fails

to teach or suggest that the polymers for the Kaplan "surgical devices," e.g., pins, bone screws, or the like, would be useful in the context of a stent.

In response to the language of the Office action, the entirely non-specific "manufacturing and surgical considerations" that are implied as being important to Stinson, are not identified or discussed in any detail in the Office action. The "considerations" are simply, in a conclusory manner, indicated to be important, and also to be satisfied by the use of the Kaplan polymeric materials. Moreover, this is all accomplished according to the rejection without any discussion of what these specific Stinson "considerations" are, and additionally without any mention of how any one or more of the Stinson "considerations" is believed to either overlap, have any commonality with, achieve any benefit from, or otherwise generally or specifically relate to the use of a polymeric material described in the Kaplan reference. These important points are emphasized here because without identifying or offering any detail or discussion of what the Examiner considers to be "manufacturing and surgical considerations" of the Stinson reference, and further without a discussion of how the polymeric materials of Kaplan achieve or fulfill these "considerations," a rejection based on these non-specific Stinson "considerations," and the conclusion that the Stinson "considerations" are realized by use of the Kaplan materials, remains nothing more than an unsupported conclusion.

Overall, neither cited reference, based on the nebulous rationale of "manufacturing and surgical considerations," has been shown to provide a requisite suggestion or motivation to use the specific polymeric materials of Kaplan, in the stents of Stinson. Accordingly, the rejection of claims 8-14, 46-53, and 59-60, as obvious, remains unsupported and should be withdrawn.

New Claims 66-75

New claims 66-75 have also been presented. These claims depend from independent claim 46 (braided stent embodiment) or from claim 61 (fenestrated stent embodiment).

The subject matter of claims 66-75 is supported throughout the specification, for example, at page 8, line 12; page 9, lines 3-6; page 9, line 20; and page 10, lines 19-29. No new matter has been added.

Applicants consider that these newly presented claims are fully understandable and require, at most, only cursory review by the Examiner. Applicants therefore respectfully request entry of the current amendment as it is viewed to advance prosecution of the current application, and to present allowable subject matter. Furthermore, the entry of the current amendment would place the rejected claims in better form for consideration on appeal, should an appeal become necessary.

The newly presented claims further exemplify the utility provided by the present invention, wherein a blend of homopolymers is used to fabricate a stent. As presented in the current specification, blends of hompolymers used to produce bioresorbable stents can exhibit certain very desirable functional properties such as strength and a useful (e.g., extended) *in vivo* lifetime.

The identification of an extended *in vivo* lifetime may be considered to be particularly useful, and even unexpected, because prior to the invention, one of skill might have expected that a blend of homopolymers would result in a stent having *reduced* strength and *in vivo* lifetime. The molecular arrangement (e.g., morphology) of polymers in a homogenous preparation (e.g., a single non-blended polymeric material) is typically ordered. It is normally expected that an ordered arrangement results in properties such as relatively higher strength and longer *in vivo* lifetime. For example, amorphous PLLA (non-ordered arrangement) hydrolyzes more rapidly than more crystalline forms of PLLA (ordered arrangement). Therefore, one might have predicted that adding another material to an ordered homogeneous material (e.g., in the form of a homopolymer blended with another homopolymer) would reduce the level of order of the composition, and thereby reduce strength of the material.

However, embodiments of the invention were contrary to these expectations, in that blended materials were observed to exhibit improved resistance to hydrolysis. The addition of only a small amount of poly-ε-caprolactone to poly-L-lactide, for example, had a dramatically improved effect on reducing the susceptibility of the resultant blend to hydrolysis, i.e., a small amount of poly-ε-caprolactone caused the in-vivo lifetime to increase. In addition, stents made from a blend of poly-ε-caprolactone to poly-L-lactide (see the CL-10 stents in the patent application figures) had greater compression resistance and greater initial self-expansion force compared to stents of pure poly-L-lactide.

In view of the amendments and remarks provided herein, Applicants view that the all of the pending claims are in condition for allowance, and respectfully request notification thereof.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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